

REMARKS/ARGUMENTS

The objection under 35 USC §112 is corrected with this amendment to claims 1 and 10.

All the claims continue to be rejected under 35 USC §102(a) or 35 USC §103(a) as being anticipated or rendered obvious by U.S. Patent No. 6,558,733 to Hossainy. Hossainy discloses stent 10 comprising a plurality of filaments 22 and interconnecting elements 24 in which one or more microdepots or pores 30 for carrying substances are formed. The filaments 22 and interconnecting elements 24 may be straight, sinusoidal, v-shaped, or may have other shapes. Importantly, the depots 30 of Hossainy are not through openings, as they have a depth D1 from about 10% to 90% of the thickness of the filament or interconnecting element in which they are formed. *See, e.g.*, Col 5, lines 36-55. It is noted that a depth greater than about 65% may compromise the structural integrity and mechanical functionality of the stent, thus teaching *away from* the present claims.

Claim 1, from which claims 2-9 and 31-32 depend, defines an expandable medical device for delivery of a beneficial agent, the device comprising a substantially cylindrical device which is expandable from a cylinder having a first diameter to a cylinder having a second diameter, the substantially cylindrical device comprising a plurality deformable members and non-deformable members, a first plurality of through openings formed in the substantially cylindrical device containing a first beneficial agent for delivery to tissue, wherein the first through openings are positioned on first and second ends of the cylindrical device, and a second plurality of through openings formed in the substantially cylindrical device containing a second beneficial agent for delivery to tissue, wherein the second through openings are positioned on a central portion of the cylindrical device between the first and second ends, and wherein the second beneficial agent is different than the first beneficial agent. The first through openings and the second through openings are positioned on the non-deformable members. Moreover, with the amendments made herein, the claims of “through openings” is now more explicit.

By providing a substantially cylindrical device comprising a plurality of deformable members and non-deformable members, it is possible to control the manner in which the device

expands from the first diameter to the second diameter by limiting deformation to the deformable members. At the same time, deformation of the first through openings and the second through openings that might adversely affect the introduction of drugs in the through openings can be limited.

The Examiner has not pointed to anywhere in the specification of Hossainy where there is disclosed filaments more or less deformable than the interconnecting members; and Hossainy does not disclose providing depots only in one of the filaments or the interconnecting members. In fact, Figure 4(c) of Hossainy, pointed out by the Examiner, shows exactly the opposite. In view of the differences between claim 1 and Hossainy, it is respectfully submitted that claim 1 and the claims dependent therefrom, including claims 2-9, are not anticipated or rendered obvious by Hossainy. Hossainy also certainly does not disclose the claimed through openings. Withdrawal of the rejection is urged.

Claim 10, from which claims 11-16 and 33-34 depend, as amended, defines a tissue supporting device comprising a tissue supporting device body configured to support a bodily lumen, the tissue supporting device comprising deformable and non-deformable members, a first beneficial agent contained in first through openings in the tissue supporting device for delivery to tissue, wherein the first through openings are positioned on first and second ends of the device body, and a second beneficial agent contained in second through openings in the tissue supporting device for delivery to tissue, wherein the second through openings are positioned on a central portion of the device body between the first and second ends. The first through openings and the second through openings are positioned in the non-deformable members.

By providing a tissue supporting device comprising a plurality of deformable members and non-deformable members, it is possible to control deformation of the device by limiting deformation to the deformable members. At the same time, deformation of the first through openings and the second through openings that might adversely affect the introduction of drugs in the through openings can be limited.

Hossainy does not disclose that the filaments are more or less deformable than the interconnecting members and does not disclose providing depots only in one of the filaments or the interconnecting members. Hossainy also certainly does not disclose the claimed through openings.

In view of the differences between claim 10 and Hossainy, it is respectfully submitted that claim 10 and the claims dependent therefrom, including claims 11-16 and 33-34, are not anticipated by and define patentably over Hossainy. Withdrawal of the rejection also is invited.

Claim 17, from which claims 18-19 depend, defines an expandable medical device for delivery of a beneficial agent. The device comprises a device body which is expandable from an initial configuration to an expanded configuration defining a cylinder having end holes at opposite ends of the device, a side hole in the device body between the opposite ends and having a center axis substantially perpendicular to a longitudinal axis of the device body and configured to accommodate a bifurcation in a lumen, a first plurality of through openings formed in the device body containing a first beneficial agent for delivery to tissue at the expanded configuration, wherein the first through openings are formed in an area surrounding the side hole, and a second plurality of through openings formed in the body device in an area away from the side hole.

Hossainy does not disclose a combination of features including a side hole having a center axis substantially perpendicular to a longitudinal axis of the device body. Holes at the ends stent and the lumen itself do not define a side hole as defined in claim 17. Hossainy also certainly does not disclose the claimed through openings.

In view of the differences between claim 17 and Hossainy, it is respectfully submitted that claim 17 and the claims dependent therefrom are not anticipated by and define patentably over Hossainy. Withdrawal of the rejection is urged.

Claim 20, from which claims 21-24 depend, as amended, defines a method of reducing restenosis in a body passageway, the method comprising positioning a tissue supporting device comprising deformable and non-deformable members in a body passageway to support the tissue, the tissue supporting device containing a first and a second beneficial agent in through openings positioned in the non-deformable members in the device, and delivering the first beneficial agent to tissue at locations adjacent ends of the tissue supporting device and the second beneficial agent to tissue between the ends of the device to reduce restenosis.

By positioning a tissue supporting device comprising deformable and non-deformable members in a body passageway to support the tissue, with a first and a second beneficial agent in through openings positioned in the non-deformable members in the device, the possibility of improper introduction of the beneficial agent due to deformation of an through opening is reduced.

Hossainy does not disclose that the filaments are more or less deformable than the interconnecting members and does not disclose providing depots only in one of the filaments or the interconnecting members. Hossainy also certainly does not disclose the claimed through openings.

In view of the differences between claim 20 and Hossainy, it is respectfully submitted that claim 20 and the claims dependent therefrom, including claims 21-24, are not anticipated by and define patentably over Hossainy. Withdrawal of the rejection is requested.

Claim 25, from which claims 26-28 and 35 depend, as amended, defines an expandable medical device for delivery of a beneficial agent. The device comprises a substantially cylindrical device which is expandable from a cylinder having a first diameter to a cylinder having a second diameter, the substantially cylindrical device comprising deformable and non-deformable members, a first plurality of through openings formed in the substantially cylindrical device containing the beneficial agent in a first concentration, and a second plurality of through openings formed in the substantially cylindrical device containing the beneficial agent in a

second concentration, wherein the first and second through openings are arranged to deliver a uniform distribution of a drug to the tissue of a body passageway. The first through openings and the second through openings are positioned in the non-deformable members.

Hossainy does not disclose that the filaments are more or less deformable than the interconnecting members and does not disclose providing depots only in one of the filaments or the interconnecting members. Hossainy also certainly does not disclose the claimed through openings.

In view of the differences between claim 25 and Hossainy, it is respectfully submitted that claim 25 and the claims dependent therefrom, including claims 26-28 and 35, are not anticipated by and define patentably over Hossainy. Withdrawal of the rejection also is requested.

Claim 41, from which claims 42-53 depend, defines a tissue supporting device comprising a generally cylindrical tissue supporting device body configured to support a bodily lumen, a plurality of first through openings in the tissue supporting device body, wherein the first through openings contain a first beneficial agent, and a plurality of second through openings in the tissue supporting device body, wherein the second through openings contain a second beneficial agent.

The depots 30 in Hossainy are not through openings, and Hossainy teaches away from the use of through openings on the grounds that too deep of an through opening will reduce the structural integrity of the filament or interconnecting element. Col. 5, lines 51-53.

In view of the differences between claim 41 and Hossainy, it is respectfully submitted that claim 41 and the claims dependent therefrom, including claims 42-53, are not anticipated by and define patentably over Hossainy. These rejections are also traversed.

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It is respectfully submitted that all of the pending claims are in condition for allowance. Allowance is cordially urged.

To the extent that the Applicant does not respond to a particular comment in the Official Action, the Applicant does not intend by this to indicate acquiescence in or agreement with the comment. To the extent that any extensions of time are necessary in connection with this application it is requested that there be a standing petition of time and that any additional fees that are required, or refunds due, in connection with this or any other paper filed in connection with this application be charged to Deposit Account 10-0750/CMI5007USNP1/PAC.

If the Examiner is of the opinion that a telephone conference would be helpful in resolving any outstanding issues, the Examiner is urged to contact the undersigned.

Respectfully submitted,

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